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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,047	06/23/2005	Vili Ravanko	18320	6216
272 7590 12/13/2007 SCULLY, SCOTT, MURPHY & PRESSER, P.C. 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER ISSAC, ROY P	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,047	Applicant(s) RAVANKO ET AL.	
	Examiner Roy P. Issac	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-16,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-16, 18-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

Rejections Withdrawn

All rejections and objections made with respect to the cancelled claims, claims 17 and 20-21 in the previous office action are withdrawn.

Applicants' amendments to claim 18 and 19 deleting "10%" and "1.5%" respectively, overcomes the rejection of claims 18 and 19 under section 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The recitation of the ranges "more than 65 weight %", "at least 65%", "at least 75%", "over 85 weight %", "90 to 96% or more", "less than 3 weight %" and "less than 1.5 weight %" renders the claims indefinite since the claimed ranges lack upper or lower limits.

Response to Arguments

Applicant's arguments filed 10/30/07 have been fully considered but they are not persuasive. Applicants argue that one of ordinary skill in the art understands the term to represent that at least a certain amount of trimers have been removed from the feed solution, that a minimal amount of saccharide monomers has been removed from the feed, or that there is a minimal amount of yield respectively, depending on the context. The applicants further argue that the recitation "at least" has been held as not indefinite. This argument was found unpersuasive since there is no indication, disclosure or reason for one of skill in the applicant to determine the upper limit of the claimed ranges. Open-ended numerical ranges should be carefully analyzed for definiteness. MPEP 2173.05(c). The claims herein are directed to methods of purifying disaccharide feed solutions and one of skill in the art would not be able to ascertain an upper limit at which the functional descriptions of the claims are accomplished. As such one of skill in the art would not be able ascertain the metes and merits of the claims herein. A patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. The purpose of the definiteness requirement is to "ensure that the

claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." *Datamize*, 417 F.3d at 1347 (internal citation omitted). Claims are considered indefinite when they are "not amenable to construction or are insolubly ambiguous ... Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning." *Id.* Indefiniteness requires a determination whether those skilled in the art would understand what is claimed. In the face of an allegation of indefiniteness, general principles of claim construction apply. *Id.* at 1348. The Federal Circuit in *Amgen, Inc. v. Chugai* held that a word of degree can be indefinite when it fails to distinguish the invention over the prior art and does not permit one of ordinary skill to know what activity constitutes infringement. 927 F.2d 1200, 1218 [18 USPQ2d 1016] (Fed. Cir. 1991). The recitation "at least about 160,000" have been held indefinite. *Id.* at 1203. Distinguishing what infringes from what doesn't is the role of the claims. The rejection under section 112, second paragraph is deemed proper and is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 5-16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heikkila et. al. (Of Record) in view of Masuda et. al. (U. S. Patent No. 5,391,299; Of record).

Heikkila et. al. discloses a method for fractionating a solution into two or more fractions by a chromatographic simulated moving bed process. (Abstract). Heikkila et. al. discloses Finex CS 13 GC, a polystyrene matrix crosslinked with divinylbenzene (DVB). (Column 14, lines 50-56). Heikkila et. al. discloses the use of Finex columns crosslinked with 5.5% DVB to separate sucrose, a disaccharide from trisaccharides and monosaccharides. (Columns 7 to 8, Example, 1, Table 1B, and Table 1C). The trisaccharides and monosaccharides in the feed solution was present as 2.8% and 0.6% weight of dry solid weight respectively. (Column 8, Table 1B). Heikkila et. al. further discloses the use of Purolite PCR 651 with 5.5% DVB for purification of sucrose, without any other saccharides. (Example 5, Columns 12-13, Tables 5A and 5B). Heikkila discloses molasses and starch hydrolysates as suitable feed solution. A separation temperature of 80°C is disclosed. (Example 2).

Heikkila et. al. does not expressly disclose the use of a feed solution with more than 65% weight % of saccharide dimer or the ranges of monomer/trimer claimed herein or the saccharification involving alpha-amylase or maltogenic alpha-amylase or a crystallization step.

Masuda et. al. discloses moving bed type fractionating method for the separation of maltose, a disaccharide from a discaccharide (maltose) content of 30-50% by weight

resulting in maltose purity of 80% by weight. (Abstract; Column 16, lines 60-65).

Matsuda further note that it is general practice to purify maltose product by crystallization. (Column 1, lines 45-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an ion exchange resin with a degree of crosslinking of 5 to 8% followed by another ion exchange resin of a degree of crosslinking of 2 to 4.5% to separate saccharide dimer from monomers and trimers and to use an ion exchange resin with a low degree of crosslinking in a further step because Heikkila et. al. teaches the use of two different types of chromatographic columns to purify saccharide dimers in particular maltose from feed solutions.

One of ordinary skill in the art would have been motivated to use an ion exchange resin with crosslinking of 5 to 8% and an ion exchange resin of 2 to 4.5% crosslinking to purify disaccharides from feed solution because Heikkila discloses the use of multiple ion exchange resins to purify saccharide solutions. Furthermore, double purification using two different types of resins would have been within the grasp of one of ordinary skill in the art without significant innovation to result in the invention as claimed. Choosing appropriate resins for the purification of feed solutions of saccharides with varying ranges of saccharide concentration is considered well within the grasp of one of ordinary skill in the art within their routine skills. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). The recitation "process resulting in a separated

saccharide dimer fraction by removal of at least 75% of the saccharide trimers from the feed solution and/or by removal of at least 65% of the saccharide monomers from the feed solution, and resulting in a yield of saccharide dimer of over 85% weight % on dry solids basis" is considered a functional recitation of an inherent property of the method of purifying a saccharide feed solution through two types of crosslinked resins. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of an ion exchange resin with a corsslining of 2 to 4.5% along with another ion exchange resin of crosslinking of 5 to 8% would result in substantially similar or better effects in purification.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 10/30/07 have been fully considered but they are not persuasive. Applicants argue that, the feed solution in the '775 patent only contains a 57.6% disaccharide while the feed solution herein has a 65-85% disaccharide content. However, the feed solution exemplified in the '775 patent is substantially similar to the

lower limit of the range claimed herein. The '775 patent discloses a crosslinking polymer that reads on the crosslinking range claimed herein for purification. It is considered well within the capabilities of one of ordinary skill in the art to use a feed solution with disaccharide content that is substantially similar (57.6% vs. 65%).

Applicants further argue that the '775 patent does not disclose a resin having a high degree of crosslinking. However, the resin disclosed in the '775 patent with 5.5% crosslinking reads on the range claimed herein and thus considered a "high degree of crosslinking". Applicants further argue that the '775 patent disclose the use of two different resins. However, the claims herein do not require the use of two different resins. Claim 1 is directed to the separation of a saccharide monomer from saccharide dimer and/or saccharide trimers from saccharide monomers. Claim 1 further recite that "an ion exchange resin with a degree of crosslinking of 5 to 8% is used when saccharide monomers are separated from saccharide dimers, and an ion exchange resin with a degree of crosslinking of 2 to 4.5% is used when saccharide trimers are separated from saccharide dimers..." Since the separation of saccharide trimer from dimer is optional and the second resin is used when such separation is required, the use of lower crosslinked resin is considered an optional step. Applicants further note that the '775 patent only disclose the purity level and does not disclose the level of trimers of monomers in the purified product. However, the disaccharide purity disclosed reads on the purity claimed herein. Since the '775 patent discloses the use of a resin that reads on the crosslinking range claimed herein, one of ordinary skill in the art would expect same or substantially similar result as claimed herein. Since the Office does not

have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Applicants further argue that there is no reason to combine the teachings of the secondary reference with the primary reference. However, both references disclose methods for purifying disaccharides and the secondary reference disclose crystallization as a general method for further purifying disaccharides. As such, one of ordinary skill in the art would have had expected the combination of the teachings of the secondary reference with the teachings of the primary reference to result in an improved method for purifying disaccharides. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The rejection under section 103 is still deemed proper and is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

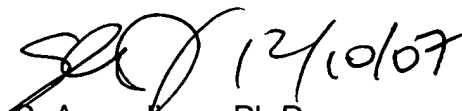
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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